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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,133	10/27/2000	Masayuki Hara	07898-061001	6449

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,133

Applicant(s)

Hara et al.

Examiner

K. P. J.

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/20/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 6, 8-26 & 29-31 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 6, 8-26 & 29-31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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The amendment of 5/20/03 amended claims 6, 8-13 and 17-23, and added new claims 29-31.

Claims examined on the merits are 6, 8-26 and 29-31 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The disclosure is objected to because of the following informalities: the abstract is not in sufficient detail. The following abstract is suggested -

Multiple cell layers are formed with one cell layer formed on another cell layer. A carrier is provided having an alginate gel layer formed on a porous membrane. An extracellular matrix component gel layer or extracellular matrix component sponge layer may be formed on the alginate gel layer. A cell layer is formed on the alginate gel layer, or the extracellular matrix component gel layer or extracellular matrix component sponge layer. The alginate gel layer is solubilized such as with a chelating agent to exfoliate the cell layer from the porous membrane, and the exfoliated cell layer is placed on another cell layer on a carrier. The number of cell layers formed on each other may be 1-10, preferably 1-5, and more preferably 1-3. --.

Appropriate correction is required.

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Claim Objections

Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Steps (a)-(c) of claim 26 are the same as steps (a)-(c) of claim 6. The steps of claim 6 will inherently form a three-dimensional tissue structure as required by the preamble and step (c) of claim 26. There is no step in claim 26 different than in claim 6 that will result in a different structure being produced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8-26 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Adequate support is not found in the specification for placing the cell layer on a different carrier as an alternative to the same carrier as required in step (c) of claims 6 and 26. The page and line of the specification where this alternative is recited should be pointed out. It is not seen how multiple layers can be formed on the carrier where the alginate is solubilized. It is suggested that "the same or another" be replaced with -- a --.

Claim Rejections - 35 USC § 112

Claims 6, 8-26 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claims 6 and 26 not specifying a relationship between the alginate gel layer and the cell layer that will result in the cell layer being exfoliated when the alginate layer is solubilized. Merely having the cell layer on the carrier will not result in exfoliating the cell layer when the alginate gel is solubilized. It is suggested that claims 6 and 26 be amended in line 2 of step (a) by after "membrane" inserting -- , and the cell layer is on the alginate layer, or on an extracellular matrix component gel layer or extracellular matrix component sponge layer which is formed on the alginate gel layer --.

Claims 6 and 26 are further unclear by reciting "same or another carrier". It is uncertain as to whether "same or another" refers to carriers being made of the same or different material, or to carriers that are separate carriers. It is not seen how multiple layers can be

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formed on the carrier where the alginate is solubilized. It is suggested that "the same or another" be replaced with -- a --.

Claim 9 should then be amended as follows:

line 1, cancel "carrier further" and insert -- cell layer is on the --;

line 2, cancel "comprises an" and "(ECM)";

line 3, cancel "which is formed on the alginate gel layer".

Claim 10 is confusing by not having antecedent basis for "the extracellular matrix component". This claim should be dependent on claim 9.

Claim 11 is unclear as to how it further limits claim 6 since claim 6 now requires multiple cell layers.

Claim 13 is confusing by requiring the porous membrane to comprise pores. A porous membrane must have pores or it will not be porous. While the specification in the paragraph beginning with "The term "porous membrane" defines a porous membrane as having pores or cavities, no membrane is described having cavities and not pores that will be permeable to a chelating agent as required by the definition of a porous membrane. It is not seen how a chelating agent can pass through a membrane not having pores. Unless it can be established that membranes are known that have cavities instead of pores that will be permeable to a chelating agent, claim 13 should be deleted. Claim 14 should be amended to depend on claim 6, and in line 1 before "pores" insert -- membrane has --, and after "pores" insert -- that --.

Claim 22 is confusing by not having antecedent basis for adding cells to the alginate gel layer. The claim should be amended as follows:

line 1, after "wherein" insert -- when forming the cell layer --;

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line 2, after "layer" insert -- , or the extracellular matrix component gel layer or extracellular matrix component sponge layer --.

Claim 23 is unclear as to how it further limits claim 6 since claim 6 requires solubilizing the alginate gel layer to exfoliate a cell layer. This solubilizing will inherently detach cells.

The claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Friday from about 9:30 AM to about 6:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DMN
8/11/03


DAVID M. NAFF
PRIMARY EXAMINER
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